February 6, 2001, yet the Office Action of April 24, 2001 indicates that claims 1-36 were not considered, yet claim 92, which depends from claim 1, was rejected.

By the present preliminary amendment new matter has been added to the specification and claims 1, 3, 7-18, 30, 32, 36, 92-93, and 95-102 have been rewritten. A marked-up version of the replacement and added paragraphs in the specification and the rewritten claims is attached as separate pages to this amendment and is titled "Version With Markings to Show Changes Made." Claims 1-36 and 92-105 of the present application retain pendency from the parent application (claims 103-105 being canceled herein). An information disclosure statement and copies of references cited are also enclosed. Please note the following newly cited references: European Patent Application No. 0 619 369 A1 and Dephosphorylation of Phytate Compounds by Means of Acid Phophatase from *Aspergillus Niger*, Zyla et al., *J. Sci. Food Agric.*, Vol. 49, pp. 314-324 (1989).

In the Office Action of April 24, 2001, the Examiner maintained the rejection of claims 92-102 under 35 USC §102(b) as being anticipated by EP 0 380 343. Applicants strongly traverse the rejection. (Although the rejection was not applied against claim 1 and its dependent claims in the Office Action of April 24, 2001, the following arguments are applicable relative to the outstanding rejection of claim 1 and its dependent claims under 35 USC §102(b)).

Claim 92, as amended, and its dependent claims provide a method of producing a soy protein material in which an aqueous slurry of a soy protein material is treated with an enzyme preparation containing an acid phosphatase enzyme to degrade ribonucleic acids in the soy protein material. The EP reference discloses treating a soy protein material with a phytate degrading enzyme to degrade phytates in the soy protein material, where acid phosphatase is disclosed as one phytate degrading enzyme that may be selected to degrade phytates in accordance with the teaching of the reference.

The burden of establishing a prima facie basis to deny patentability rests upon the Examiner. *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency to establish anticipation, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art. *In re King*,

231 USPQ 136 (Fed. Cir. 1986); *Ex parte Levy*, 17 USPQ2d 1461 (PTOBPAI 1990). In order for the allegedly inherent characteristic to **necessarily** flow from the teaching of the prior art the characteristic must be the natural result flowing from the operation as taught, and the mere fact that certain thing **may** result from a given set of circumstances is not sufficent. *Mehl/Biophile International Corp. v. Milgraum*, 52 USPQ2d 1303 (Fed Cir. 1999).

In the present case the Examiner has failed to establish a prima facie basis to deny patentablility of the claims by inherent anticipation of the claims as amended because the Examiner has failed to prove 1) that a soy protein material is **necessarily** treated with an enzyme preparation containing an acid phosphatase enzyme as a result of the teaching of EP 0 380 343 and 2) that degradation of ribonucleic acids in a soy protein material is a **necessary** result of practicing the teaching of EP 0 380 343. However, the Examiner continues to maintain that degrading ribonucleic acids in a soy protein material with an enzyme preparation containing an acid phosphatase enzyme is an inherent result of practicing the teaching of EP 0 380 343.

In order for the Examiner to establish inherent anticipation in the present case, the ribonucleic acids in a soy protein material must always (**necessarily**) be degraded by an enzyme preparation containing an acid phosphatase enzyme in the practice of the process disclosed by the EP reference; and a soy protein material must always (**necessarily**) be treated with an enzyme preparation containing an acid phosphatase enzyme in the process of the EP reference. The EP reference, however, is not limited in such a manner.

The EP reference is not limited to the use of an enzyme preparation containing an acid phosphatase, and as such, does not always result in the degradation of ribonucleic acids. As stated on page 6 lines 38-40 of the EP reference "Stated most simply, in its broadest terms the present invention comprises: (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate degrading enzymes...". The language of the EP reference does not state that the enzyme preparation comprises an acid phophatase enzyme plus one or more further phytate degrading enzymes, and does not state at any point in the disclosure that an acid phosphatase enzyme **is required or necessary** in the phytate degrading enzyme preparation. To the contrary, the EP reference discloses that phytate-degrading enzymes

include phytase and acid phosphatase (page 6 line 19), which in light of the statement of invention set forth in the reference clearly indicates that the process of the EP reference can be performed by using a phytase enzyme without an acid phosphatase enzyme.

The EP reference, therefore, provides one skilled in the art with a selection of phytate degrading enzymes which are useful for degrading phytates in soy protein materials. The selection includes, but is not limited to and does not necessarily include, acid phosphatase enzymes. Selection and use of one or more phytate degrading enzymes in accordance with the teaching of the EP reference for degrading phytate in a soy protein material **may or may not** result in selection of an enzyme preparation containing an acid phosphatase enzyme which degrades ribonucleic acids in the soy protein material in accordance with the claimed invention. For example, one skilled in the art may select 3-phytase to practice the process disclosed in the EP reference. As described in the Applicants' previous response, selection of 3-phytase will enable degradation of phytates in a soy protein material in accordance with the EP reference, but will not anticipate the claims of the present invention since 1) the soy protein material is not treated with an enzyme preparation containing an acid phosphatase enzyme as required by the claims; and 2) ribonucleic acids in the soy protein material are not degraded as required by the claims. In short, the claims are not anticipated inherently by the disclosure of the EP reference because the EP reference provides a selection of phytate-degrading enzymes which are not limited to acid phosphatase containing enzyme preparations, and therefore the claimed elements of 1) treating an aqueous slurry of a soy protein material with an enzyme preparation containing an acid phosphatase enzyme and 2) degrading ribonucleic acids in a soy protein material with an enzyme preparation containing an acid phosphatase enzyme **do not necessarily flow** from the teaching of the EP reference.

Analysis of the *Mehl/Biophile International Corp.*(cite *supra*) inherent anticipation discussion reveals a similar situation to the alleged inherent anticipation in the present case. The claims in the *Mehl/Biophile* case were directed to a method of dipilating hair follicles with a laser in which a laser was substantially vertically oriented to the hair follicle and the laser was pulsed to irradiate the papilla of the hair follicle so that hair regrowth was prevented. The papilla of the hair follicle lies at the base of the hair within the skin, so the vertical orientation of the laser was necessary to irradiate the

papilla. The alleged anticipatory reference disclosed the use of a similar laser and laser pulse applied to the skin to remove tattoos from the skin without scarring. The court found that the article did not explicitly anticipate the claims because it did not teach hair depilation, and did not inherently anticipate the claims because the laser, as used in the reference, was not required **necessarily** to be aligned vertically over the hair follicle. The court went on to state that even though the laser, as used in the reference, may possibly align vertically to the hair follicle such that irridation of the papilla occurred and hair dipilation resulted, that such an alignment did not legally suffice to show inherent anticipation because occasional results are not inherent.

A similar situation presents itself in the present case. One may practice the teaching of the EP reference using an enzyme preparation containing an acid phophatase enzyme to degrade phytates in a soy protein material (and degrade ribonucleic acids as well without being aware of such degradation), but one may also use an enzyme preparation containing phytases with no acid phosphatase to degrade phytates in a soy protein material. According to the logic of the *Mehl* case, the EP reference cannot legally suffice to show anticipation of the present claims because occasional results are not inherent. Even though use of an enzyme preparation containing an acid phosphatase enzyme in a soy protein material necessarily results in degradation of ribonucleic acids in the soy protein material, such necessary results are insufficient to establish inherent anticipation of the claimed invention by the EP reference because the process of the reference is not limited necessarily to the use of an enzyme preparation containing an acid phosphatase enzyme to degrade phytate in a soy protein material.

In summary, the Examiner has stated that a prima facie case of anticipation has been established merely because the reference teaches acid phosphatase to degrade soy protein. Applicants agree that the reference teaches the use of an acid phosphatase enzyme in a soy protein material, however, Applicants insist that a mere recitation that the EP reference teaches the use of acid phosphatase to degrade soy protein is insufficient to establish inherent anticipation of the claims under the law. To establish inherent anticipation the Examiner must show that 1) use of an enzyme preparation containing an acid phosphatase enzyme in a soy protein material **is a necessary result and necessarily (always) flows from** the teaching of the reference; and 2) that degradation of ribonucleic

acids in a soy protein material with an enzyme preparation containing an acid phosphatase enzyme **is a necessary result and necessarily (always) flows from** the teaching of the reference. The Examiner has failed to make such a showing, and the reference clearly does not provide a disclosure that would enable the Examiner to make such a showing.

Added claims 106-113 are also not inherently anticipated by the EP reference. Claim 106 and its dependent claims require treatment of a vegetable protein material slurry with an enzyme preparation containing an acid phosphatase, where the enzyme preparation is used in an amount sufficient to provide an activity of greater than 500 KPU/kg of protein material. The Examples of the EP reference disclose that phytase enzyme preparations used in an amount sufficient to provide 150 PU/g protein material, 500 PU/g protein material, 750 PU/g protein material, and 1000 PU/g protein material are all effective to degrade phytates in a soy protein material. As the numerical values of KPU/kg protein material and PU/g protein material are equivalent, it is clear that use of an enzyme preparation containing acid phosphatase in an amount sufficient to provide greater than 500 KPU/kg protein material **is not a necessary result and does not necessarily flow from** the teaching of the reference. Claims 106-113, therefore, are not inherently anticipated by the EP reference.

In light of the above, Applicants respectfully request allowance of all the claims remaining in the application.

Respectfully submitted,

WONG ET AL

Date: May 3, 2001

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

Immediately after the title the following sentence has been inserted:
--This application is a continuation-in-part of co-pending application Serial No. 08/996,976 filed on 12/23/97.--

On page 4 the following paragraph has been inserted between the paragraph ending on line 18 and the paragraph starting on line 19:

--The starting material for the process of the present invention is a vegetable protein material which contains protein and ribonucleic acids. The vegetable material may be relatively unrefined, for example whole soybeans and whole peas. More preferably the vegetable material is more refined and is processed to remove fats, oils, and hulls, and is comminuted or flaked. Preferred moderately refined vegetable protein materials are vegetable flour, vegetable grits, and vegetable flakes. Especially preferred moderately refined vegetable protein materials are defatted soy flours, defatted soy grits and soy meals, and defatted soy flakes.--

On page 4 the paragraph starting on line 19 (lines 19-27) has been amended as follows:

Most preferably the [The] starting material for the process of the present invention is a refined vegetable protein material such as a vegetable protein concentrate or a vegetable protein isolate. As used herein, and according to conventional definition, a vegetable protein concentrate is a vegetable protein material containing from 65% [-] up to 90% protein by weight on a dry basis, and a vegetable protein isolate is a vegetable protein material containing at least 90% protein by weight on a dry basis. Vegetable protein concentrates and isolates are readily commercially available. For example, soy protein isolates which may be used in the process of the present invention are available from Protein Technologies International, Inc., St. Louis, Missouri, and are sold under the trade names SUPRO® 500E and SUPRO® 620.

On pages 6-7 the paragraph starting on line 23 of page 6 and continuing to line 2 of page 7 has been split into two paragraphs and amended as follows:

The enzyme preparation is added to the slurry in sufficient amount to provide an acid phosphatase concentration effective to degrade and substantially reduce the concentration of ribonucleic acids present in the protein material. The enzyme preparation has an inherent specific enzyme activity measured as phytase units per gram (if the enzyme preparation is a solid) or phytase units per milliliter (if the enzyme preparation is a liquid), where a phytase unit is defined as, and may be measured as, the quantity of enzyme which liberates one nanomole of inorganic phosphates from sodium phytate in one minute under standard conditions (40°C, pH 5.5, and 15 minutes incubation). Commerically available phytase enzyme preparations typically disclose the inherent phytase activity of the enzyme preparation (e.g. 40 PU/g of preparation), or, if the enzyme preparation's phytase activity is unknown, it may be measured under

standard conditions as set forth above. To effectively degrade and substantially reduce the concentration of ribonucleic acids in the vegetable protein material, the enzyme preparation is preferably used in an amount sufficient to provide an enzyme activity of greater than 500 kilophytase units per kilogram of protein material ("KPU/kg protein material"), and more preferably at least 600 KPU/kg protein material, or at least 700 KPU/kg protein material, or at least 800 KPU/kg protein material, or at least 900 KPU/kg protein material, or at least 1000 KPU/kg protein material, or at least 1100 KPU/kg protein material, or at least 1200 KPU/kg protein material, or at least 1300 KPU/kg protein material, or at least 1400 KPU/kg protein material, where a kilophytase unit is defined as 1000 phytase units.

Preferably at least a majority of the ribonucleic acids present in the initial vegetable protein material are degraded by the acid phosphatase containing enzyme preparation, where the term a majority is defined to be 50% or greater. More preferably, the acid phosphatase containing enzyme preparation degrades at least 60% of the ribonucleic acids in the vegetable protein material, even more preferably at least 70% of the ribonucleic acids in the protein material, and even more preferably at least 80% of the ribonucleic acids in the protein material, and most preferably the acid phosphatase containing enzyme preparation degrades substantially all of the ribonucleic acids in the protein material.

On pages 7-8 the paragraph starting on line 29 of page 7 and ending on line 9 of page 8 has been amended as follows:

The activity of the enzyme preparation should be effective to degrade and substantially reduce the concentration of ribonucleic acids, the phytic acid concentration, and the concentration of phytates. The enzyme preparation preferably [has] is used in an amount sufficient to provide an activity from about 400 to about 1400 kilophytase units per kilogram of protein (curd) solids (KPU/kg protein [solid] solids), more preferably [has] an activity of from about 600 to about 1200 KPU/kg protein [solid] solids, and most preferably [has] an activity of about 1000 KPU/kg protein [solid] solids. [A kilo phytase unit equals 1000 phytase units, where a phytase unit equals the quantity of enzyme which liberates one nanomole of inorganic phosphates from sodium phytate in one minute under standard conditions (40°C, pH 5.5, and 15 minutes incubation).] The activity of the enzyme preparation includes acid phosphatase activity and the activity of any other phytase enzyme included in the enzyme preparation.

On page 10 the following paragraph has been inserted between the paragraph ending on line 7 and the paragraph beginning on line 8.

--The vegetable protein material of the present invention is devoid or substantially devoid of active, inactivated, or hydrolyzed ribonuclease enzymes and contains at most 4000 milligrams per kilogram ("mg/kg") ribonucleic acids, more preferably 2000 mg/kg or less of ribonucleic acids, and most preferably 1500 mg/kg or less of ribonucleic acids. Preferably the vegetable protein material of the present invention contains 0.45% or less phytic acid, by weight, more preferably 0.2% or less phytic acid, by weight, and most preferably 0.1% or less phytic acid, by weight. In a particularly preferred embodiment the vegetable protein material of the present invention contains less than 3000 parts per million (ppm) phosphorus. Most preferably the vegetable protein material is a soy

protein material, and particularly preferred soy protein materials are soy protein isolates and soy protein concentrates.--

In the Claims

Claims 1, 3, 7-18, 30, 32, 36, 93, and 95-101 have been amended as follows:

1. (Amended 4 times)

A method for producing a soy [vegetable] protein material[,] comprising,

forming an aqueous slurry of a soy [vegetable] protein material;

treating the slurry with an enzyme preparation containing an acid phosphatase enzyme at a temperature, a pH, and for a time period effective for said [acid phophatase] enzyme preparation to degrade ribonucleic acids in the soy [vegetable] protein material; and

washing the soy [vegetable] protein material to remove degraded ribonucleic acids.

3. (Amended) The method of claim 1 [2] wherein said soy [vegetable] protein material is a soy protein concentrate or a soy protein isolate.

7. (Amended) The method of claim 1 wherein treatment of said slurry with said enzyme preparation is effective to degrade a majority of ribonucleic acids in said soy [vegetable] protein material.

8. (Amended) The method of claim 7 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy [vegetable] protein material from which a majority of ribonucleic acids have been removed.

9. (Amended) The method of claim 1 wherein treatment of said slurry with said enzyme preparation is effective to degrade at least 60% of ribonucleic acids in said soy [vegetable] protein material.

10. (Amended) The method of claim 9 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy [vegetable] protein material from which at least 60% of ribonucleic acids have been removed.

11. (Amended) The method of claim 1 wherein treatment of said slurry with said enzyme preparation is effective to degrade at least 70% of ribonucleic acids in said soy [vegetable] protein material.

12. (Amended) The method of claim 11 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy [vegetable] protein material from which at least 70% of ribonucleic acids have been removed.

13. (Amended) The method of claim 1 wherein treatment of said slurry with said enzyme preparation is effective to degrade at least 80% of ribonucleic acids in said soy [vegetable] protein material.

14. (Amended) The method of claim 13 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy [vegetable] protein material from which at least 80% of ribonucleic acids have been removed.

15. (Amended) The method of claim 1 wherein treatment of said slurry with said enzyme preparation is effective to degrade substantially all of ribonucleic acids in said soy [vegetable] protein material.

16. (Amended) The method of claim 15 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy [vegetable] protein material from which substantially all [of] ribonucleic acids have been removed.

17. (Amended) The method of claim 1 wherein treatment of said slurry with said enzyme preparation is effective to degrade phytic acid and phytates in said soy [vegetable] protein material.

18. (Amended) The method of claim 17 wherein washing the treated slurry is effective to remove said degraded phytic acid and phytates to provide a soy [vegetable] protein material from which phytic acid and phytates have been removed.

30. (Amended) The method of claim 1 further comprising a step of drying said treated and washed slurry to provide a purified soy [vegetable] protein material.

32. (Amended) The method of claim 1 further comprising a step of treating said washed and acid phosphatase treated soy [vegetable] protein slurry with a protease enzyme at a temperature, pH, and for a time sufficient to hydrolyze said protein in said slurry.

36. (Amended) The method of claim 1 wherein said treatment of said soy [vegetable] protein material slurry with an enzyme preparation containing an acid phosphatase and said wash of said treated slurry are effective to lower the mineral content in the soy [vegetable] protein material.

92. (Amended) The method of claim 1 wherein said soy [vegetable] protein material is washed by diluting said treated slurry with water and subsequently removing at least a portion of said diluent from said soy protein material.

93. (Twice amended)

A method of producing a soy [vegetable] protein material[,] comprising, treating an aqueous slurry of a soy [vegetable] protein material with an enzyme preparation containing an acid phosphatase enzyme at a temperature, a pH, and for a time period effective for said [acid phosphatase] enzyme preparation to degrade ribonucleic acids in the soy [vegetable] protein material.

95. (Amended) The method of claim [94] 93 wherein said soy [vegetable] protein material is a soy protein concentrate or a soy protein isolate.

96. (Amended) The method of claim 93 wherein treatment of the slurry with said enzyme preparation is effective to degrade a majority of ribonucleic acids in the soy [vegetable] protein material.

97. (Amended) The method of claim 93 wherein treatment of the slurry with said enzyme preparation is effective to degrade at least 80% of ribonucleic acids in the soy [vegetable] protein material.

98. (Amended) The method of claim 93 wherein said enzyme preparation is effective to degrade phytic acid and phytates in said soy [vegetable] protein material.

99. (Amended) The method of claim 93 wherein said slurry is treated with an enzyme preparation containing an acid phosphatase at a pH of about 3 to 6.

100. (Amended) The method of claim 93 wherein said slurry is treated with an enzyme preparation containing an acid phosphatase at a temperature of from about 20°C to about 70°C.

101. (Amended) The method of claim 93 wherein said slurry is treated with an enzyme preparation containing an acid phosphatase wherein said enzyme preparation [acid phosphatase] has an activity of greater than 500 KPU/kg of protein material in said slurry [about 600 KPU/g of solids to about 1400 Kpu/g of solids].

when is claim 102

In the Abstract

The abstract has been amended to read as follows:

--A method of reducing the ribonucleic acid content in a vegetable protein material is provided. A vegetable material containing protein and ribonucleic acids is treated with an enzyme preparation containing an acid phosphatase to degrade the ribonucleic acids in the vegetable protein material.--